DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service
5266

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4500
Facsimile: 504-253-4560

March 8, 2001

WARNING LETTER NO. 2001-NOL-14

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. William Prestage, President
Prestage Farms, Inc.
4651 Taylors Bridge Hwy
Clinton, North Carolina 28328

Dear Mr. Prestage:

An inspection of your medicated and non-medicated animal feed operation, located at West Churchhill Road, West Point, Mississippi, conducted by a U.S. Food and Drug Administration (FDA) investigator during February 21-22, 2001, found significant deviations from the Current Good Manufacturing Practice (CGMP) requirements for Medicated Feeds, Title 21, *Code of Federal Regulations*, Part 225 (21 CFR). Such deviations cause the medicated feeds manufactured at your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found your firm failed to conduct potency assays on at least three representative samples of each feed required to be manufactured by your licensed medicated feed mill at periodic intervals during the calendar year 2000; failure to investigate and correct the cause of medicated feeds that failed assay specifications; and, failure to have master production records.

The above is not intended to be an all-inclusive list of deviations from the regulations or CGMP requirements. As a manufacturer of medicated and non-medicated animal feeds, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law. Enclosed is a copy of the FDA's Small Entity Compliance Guide to assist you with complying with the regulations.

You should take prompt action to correct these violations, and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action, such as seizure and/or injunction, and/or administrative sanctions without further notice. The sanctions may include notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Mill License, under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2). (This letter constitutes official notification under the law.) Based on the results of this inspection, evaluated with the evidence before FDA when the Medicated Feed Mill License

was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feeds are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our findings and provides you an opportunity to correct the cited deficiencies.

You should notify this office in writing, within thirty (30) working days of the receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within thirty (30) working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Mark W. Rivero, Compliance Officer, at the above address.

Sincerely,

Richard D. Debo
Acting District Director
New Orleans District

Enclosures: FDA Form 483
FDA's Small Entity Compliance Guide

cc: Mr. James R. Morton, Feed Mill Manager
Prestage Farms, Inc.
P.O. Box 1425
West Point, MS 39773
w/copy enclosure